Complete Summary

GUIDELINE TITLE

Chronic kidney disease (non-dialysis) medical nutrition therapy protocol.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Chronic kidney disease (non-dialysis) medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2002 May. Various p.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic kidney disease (non-dialysis)

GUIDELINE CATEGORY

Counseling
Evaluation
Risk Assessment
Treatment

CLINICAL SPECIALTY

Nephrology
Nutrition

INTENDED USERS

Dietitians

GUIDELINE OBJECTIVE(S)

To provide recommendations for providing nutritional care for chronic kidney disease for patients who have not yet started dialysis

TARGET POPULATION

Adults diagnosed with chronic kidney disease regardless of the cause with a glomerular filtration rate $\leq$ 60 ml/min who may show few clinical signs of the disease.

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Nutrition focused assessment including measurement of height, weight, usual weight, body mass index, glomerular filtration rate, laboratory values, other clinical data, client´s knowledge of kidney disease, and readiness to learn
2. Comprehensive diet history
3. Physical activity pattern
4. Psychosocial, economic, and co-morbid issues impacting nutrition therapy

Management/Medical Nutrition Therapy

1. Self-management
    - Low protein diets supplemented with amino acids or ketoacids
    - Intensive training in type I diabetes mellitus
2. Dietary protein
3. Monitoring of energy requirements
4. Nutrition assessment and intervention
5. Treatment for anemia
    - Erythropoietin
    - rHu-EPO (recombinant human erythropoietin)
6. Treatment for hyperphosphatemia
    - Dietary phosphate restriction and/or phosphate binders
    - Calcium
    - Vitamin D supplements
    - Self-management training
    - Protein-restricted diets
7. Prevention of cardiovascular disease with aggressive treatment of hypertension and hyperlipidemia
8. Glycemic control in diabetes

MAJOR OUTCOMES CONSIDERED

- Nutritional status (weight, muscle and fat stores, serum albumin)
- Glomerular filtration rates (GFRs)

- Blood pressure levels
- Progression of kidney disease
- Serum phosphorus levels
- Blood glucose levels

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The priorities for choosing articles to support the American Dietetics Association Medical Nutrition Therapy Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol were:

1. Randomized Controlled Trials to evaluate the effects of various factors on the progression of kidney disease. Randomized controlled trials were selected that evaluated:
    a. the effect of moderate restriction of dietary protein on microalbuminuria;
    b. the energy requirements of clients with chronic kidney disease;
    c. the effect of erythropoietin therapy in anemia of chronic kidney disease on energy levels and work capacity;
    d. the effect of dietary calcium and phosphorus on serum calcium, phosphorus, calcitriol and secondary hyperparathyroidism in chronic kidney disease.
2. Cohort Studies evaluating risk factors associated with mortality, the relationship between adherence to a very low protein diet and renal replacement therapy, and resting metabolic rate in chronic kidney disease.
3. Consensus Reports or Statements from the National Kidney Foundation (Kidney Disease Outcomes Quality Initiative [K/DOQI]) and the American Diabetes Association were used to identify recent high quality experimental studies (randomized controlled trials). Meta-analysis reviews were chosen that used statistical tests of homogeneity. Systematic reviews were chosen that provided adequate details of the studies to evaluate the quality of the research.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetics Association Health Services Research Task Force. This process in an adaptation of the US Preventive Task Force evidence analysis process.

Rating Scheme

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion (see the "Rating Scheme for the Strength of the Recommendations" field). Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Plus: indicates that the report clearly addresses issues of inclusion/exclusion, bias, generalization and data collection and analysis

Minus: indicates that above issues are not adequately addressed

Neutral: indicates that the report is neither exceptionally strong nor exceptionally weak

NA: Indicates that report is not a primary reference and therefore the quality has not been assessed

Classes of Research Reports

A. Primary Reports of New Data Collection

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports

Class M:

- Meta-analysis
- Decision analysis
- Cost-benefit analysis
- Cost-effectiveness study

Class R:

- Review article
- Consensus statement
- Consensus report

Class X:

- Medical Opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Ideal/Goal Values listed in the American Dietetic Association Medical Nutrition Therapy (ADA MNT) Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol is based on a comprehensive review of published peer-reviewed research and literature. In addition, practice guidelines and recommendations supported by national consensus committees were also used. In instances where guidelines and recommendations vary among consensus panels, the information was carefully analyzed.

Phase I in the development of the Chronic Kidney Disease (non-dialysis) Protocol includes the following steps:

Step One: Define the clinical question

Step Two: Conduct a comprehensive search of the literature

Step Three: Gather relevant articles and abstract key information

Step Four: Critique articles and rate the evidence

Step Five: Summarize and integrate results of the review

Step Six: Use the results

The levels of evidence and grading developed by the Institute for Clinical Systems Improvement (ICSI), Minneapolis, MN is the process adopted by the American Dietetic Association Health Services Research Task Force in December 2000. This process is an adaptation of the United States Preventive Services Task Force evidence analysis process. ICSI process is designed as a practical approach that is user friendly for the clinician. ICSI classifies research reports as:

1. Primary reports of new data collection
2. Reports that synthesize or reflect upon collections of primary reports

Primary reports are categorized according to the level of evidence with category A (randomized, controlled trials) having the highest level of evidence or showing cause and effect. All other primary reports (cohort studies, case studies, nonrandomized trials with concurrent controls) are only able to show an association--not cause and effect. Reports that synthesize or reflect upon collections of primary reports are meta-analysis, systematic reviews, consensus reports, or medical opinion.

Studies and reports were evaluated individually and categorized according to the class of research report and the quality of the research (positive +, neutral, negative -).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A panel of experts, including practitioners and researchers with a depth of experience in the area of practice, convened as the American Dietetics Association (ADA) Medical Nutrition Therapy (MNT) Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol Writing Group. Their tasks were: first, to agree on a set of recommendations suitable for use in usual clinical situations based on scientific evidence, and where evidence is lacking, on extensive experience and expert opinion; and second, to write the guide (i.e., recommendation) for practice.

Studies and reports within a topic (for example, the effects of restriction of dietary protein on the progression of kidney disease) were given a conclusion grade based on the available evidence. Grade I conclusion is supported by good evidence, Grade II by fair evidence, Grade III by limited evidence and Grade IV only by opinion. American Dietetic Association Medical Nutrition Therapy Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol Evidence Analysis Workgroup reached a consensus on the conclusion grade for each topic.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Dietetic Association Medical Nutrition Therapy Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol has gone through a comprehensive peer-review process for technical accuracy and content and translation to practice, and meets the criteria for level I (bronze level) validation as defined by the Quality Management Committee of the American Dietetic Association. At the bronze level, recommendations are based primarily on expert opinion and experience.

The Review Panel and Development Committee included experts in the field (experienced dietetics practitioners, specialists, researchers, and educators) and experts and opinion leaders outside the dietetics profession including a physician. The panel utilized a review form to focus feedback on important elements/criteria. In addition, the protocol was evaluated and reviewed for how reasonable

expectations are for reimbursement, a critical element for securing Medical Nutrition Therapy coverage in today´s health care market.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Conclusion grades (I-IV) are defined at the end of the "Major Recommendations" field.

Chronic Kidney Disease (non-dialysis) MNT

1. Number of MNT visits

Setting: Ambulatory Care or adapted for other health care settings
Number of encounters: 4 to 8 (Grade I)

Encounter	Length of contact	Times between encounters
1	60-90 minutes	3-4 weeks
2	45-60 minutes	3-4 weeks
3	45-60 minutes	3-4 weeks
4, 5, 6	30-45 minutes	6-8 weeks or as identified by reassessment

2. Clinical Assessment
    a. Laboratory Values:
        - Serum Albumin: >4.0 g/dL (Grade II)
        - Serum CO_2: 24-32 mEq/L (Grade II)
        - Serum Potassium: 3.5-5.5 mmol/L (Grade II)
        - Serum Calcium: 8.5-10.2 mg/dL (corrected)
        - Serum Phosphorus: 3.4-5.5 mg/dL (Grade II)
        - Intact Parathyroid Hormone: 100-300 pg/ml (Grade II)
        - (If diabetic) Random glucose: <140-160 mg/dL (blood); <160-180 mg/dL (plasma); A1C: <7% (Grade I)
        - Serum Creatinine/Glomerular Filtration Rate: stabilizes
        - Hgb: 12 g/L; 11 g/L (F) (Grade II)
    b. Nutrition/Physical
        - Blood pressure: <125/75: >1 g proteinuria or diabetic nephropathy; <130/85 without proteinuria (Grade II)
        - Height: Yearly heights to monitor spinal osteoporosis/bone loss
        - BMI: ≥24 (edema-free weight)
3. Therapeutic Lifestyle Changes

Goal: Maintain kidney function, decrease progression; maintain nutritional status Encounter in which behavioral topics are covered may vary according to client's readiness, skills, resources and need for lifestyle changes

a. Food and Meal Planning:
    - Kcal: Basal energy expenditure (consider stress, dietary protein, weight goals) (Grade I)
    - Protein: 0.6 to 1.0 g/kg/ideal body weight (IBW) based on GFR, urinary protein excretion, degree of malfunction, stress, motivation (Grade I)
    - Fat: 25-30%, <7% saturated fatty acid, <200 mg cholesterol
    - Carbohydrate: 50 to 60% kcal
    - Sodium: Individualized, 1-3 g/d
    - Potassium: Individualized based on labs
    - Phosphorus: 8-12 mg/kg IBW; phosphate binders/vitamin D analogues may be needed
    - Calcium: Individualized: ~800 to 1200 mg/d
b. Physical Activity
    - Maintains muscle stores/strength
c. Self-Monitoring
    - Dietary Intake = prescription >80% of time

Definitions:

Conclusion Grades

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design answering the questions addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results for different studies or because of doubts about generalizability, bias, research design flaws or adequacy of sample size. Alternatively, the evidence consists solely of studies from weaker designs for the questions addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from limited studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because that studies that have been done are inconclusive due to lack of generalizability, bias, design flaws or inadequate sample sizes.

Grade IV: The support of the conclusion consists solely of the statements on informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies.

CLINICAL ALGORITHM(S)

A flow chart for Medical Nutrition Therapy Process for Chronic Kidney Disease (non-dialysis) is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains conclusion statements that are supported by grading worksheets. These worksheets summarize the important studies pertaining to the conclusion. The quality of the evidence supporting key recommendations (i.e., self management, dietary protein, energy requirements, nutrition assessment and intervention, anemia of chronic kidney disease, hyperphosphatemia, prevention of cardiovascular disease, and glycemic control in diabetes) is graded (positive, negative, neutral) for each study. The type of study is also identified.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Medical nutrition therapy (MNT) has an important role in slowing the progression of chronic kidney disease while maintaining optimal nutritional status. In addition, MNT has an important role in reducing the risk for chronic kidney disease in individuals with diabetes and hypertension with MNT for those diseases. Increasing evidence indicates that the adverse outcomes of chronic kidney disease, such as kidney failure, cardiovascular disease and premature death, can be prevented or delayed.
- Studies in both type 1 and type 2 diabetes indicate that nearly all of the excess mortality associated with diabetes is found in those with albuminuria. The Diabetes Complications and Control Trial demonstrated that improvements in glycemic control as determined by A1C significantly reduced the risk for developing microalbuminuria and diabetic nephropathy. The United Kingdom Prospective Diabetes Study demonstrated a 25% reduction in microvascular events (retinal and kidney disease) and a lower prevalence of microalbuminuria and declining kidney function in the intensive treatment group.
- Studies demonstrate a positive benefit of limiting protein intake to ~0.8 g/kg ideal body weight (IBW) in early diabetic nephropathy and in nephrotic syndrome with reduction of proteinuria. In other types of kidney disease, reduction of protein intakes to 0.3 to 0.6 grams/day with amino acids and/or ketoacids has slowed the progression of kidney disease in most studies.
- Early treatment of complications of chronic kidney disease--anemia and hyperparathyroidism is important in prevention of cardiovascular disease. Correction of anemia with erythropoietin will prevent left ventricular hypertrophy and heart failure and improve the quality of life. Likewise, early treatment of hyperparathyroidism can prevent the effects of calcium/phosphorus products on cardiovascular disease as well as bone disease. Nutrition interventions for hyperparathyroidism are restricting dietary phosphorus and encouraging compliance to phosphate binders and vitamin D supplements.

POTENTIAL HARMS

Restricting diets to <0.8 g protein /kg/ideal body weight (IBW) (the Recommended Dietary Allowance for protein) may increase the likelihood of developing protein calorie malnutrition and therefore should always be used with caution and with close monitoring by the dietitian.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These nutrition practice guidelines are meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This digital media publication is an integral part of the plans for getting the American Dietetics Association Medical Nutrition Therapy Evidence-Based Nutrition Chronic Kidney Disease (non-dialysis) Protocol to all dietetics practitioners engaged in providing nutritional care, teaching, or conducting research on chronic kidney disease (non-dialysis) as quickly as possible. National implementation workshops at various sites around the country are planned. Additionally there are recommended dissemination and adoption strategies for local use of the American Dietetics Association Medical Nutrition Therapy Evidence-Based Chronic Kidney Disease (non-dialysis) Protocol.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Chronic kidney disease (non-dialysis) medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2002 May. Various p.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 May

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

American Dietetic Association Medical Nutrition Therapy Evidence-Based Chronic Kidney Disease (non-dialysis) Protocols Evidence Analysis Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print and CD-ROM copies: Available from the American Dietetic Association, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995; Phone: (800) 877-1600, ext. 5000; Web site: www.eatright.org; E-mail: sales@eatright.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003.

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